



McNeil
Consumer Healthcare
McNeil Consumer Healthcare
Washington, PA 19034-2299

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Approved by FDA on 11/15/93

Mfr report #
UF Dist report #
FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient identifier unknown In confidence	2. Age at time of event: 16 yrs or Date of birth:	3. Sex () female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 TYLENOL Analgesic Unknown #2			
B. Adverse event or product problem 1. X Adverse event and/or Product problem (e.g., defects/malfunctions) 2. Outcomes attributed to adverse event (check all that apply) () death (m/d/y/vr) () life-threatening (X) hospitalization - initial or prolonged () disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other: 3. Date of event unknown (m/d/y/vr) 4. Date of this report 09/08/99 (m/d/y/vr) 5. Describe event or problem Physician report of OVERDOSE and LIVER FUNCTION TESTS ABNORMAL (liver enzymes elevated) allegedly associated with an unspecified TYLENOL acetaminophen product in a 16 year old patient. According to physician, patient took an "overdose" of TYLENOL on an unspecified date. An unspecified time later, patient was hospitalized. At time of report, patient had been receiving "n-acetylcysteine for approximately 30 hours". Physician reports that liver enzymes remain elevated. No further information was provided. 6. Relevant tests/laboratory data, including dates unspecified date: liver enzymes reportedly elevated 7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) unknown				2. Dose, frequency & route used #1 "overdose", po #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates #2	
				4. Diagnosis for use (indication) #1 unknown #2		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A	
				6. Lot # (if known) #1 Unknown #2		7. Exp. date (if known) #1 Unknown #2	
				9. NDC # - for product problems only (if known)		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A	
				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown			
G. All manufacturers							
1. Contact office - name/address (& mfring site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034				2. Phone number 215-273-7303		3. Report source (check all that apply) () foreign () study () literature () consumer (X) health professional () user facility () company representative () distributor () other:	
				4. Date received by manufacturer (m/d/y/vr) 09/08/99		5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes	
6. If IND, protocol #				7. Type of report (check all that apply) () 5-day () 15-day () 10-day (X) periodic (X) Initial () follow-up #		8. Adverse event term(s) OVERDOSE LIVER FUNC ABNO	
9. Mfr. report number 1234586A							
F. Initial reporter							
1. Name, address & phone # [redacted] MD [redacted] Dentistry [redacted] [redacted] AUG - 9 2000							
2. Health professional? (X) Yes () No		3. Occupation Physician		4. Initial reporter also sent report to FDA () Yes () No (X) Unk			



Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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